

PodiaClave[®] User Manual

Portable Steam Sterilizer



 **Prestige Medical**[®]
Integrated decontamination solutions

Instructions for use

Please read these instructions before using the autoclave.

Keep these “Instructions for use” in a safe place close by the unit for future reference.

Service Helpline: Telephone: 01254 844 116

e.mail: customerservice@prestigemical.co.uk

The Prestige Medical Customer Service Team is available to provide advice and assistance during normal office hours. To avoid delays when making contact, please have the unit's Model and Serial Numbers at hand.

For additional information visit

www.prestigemical.co.uk

UK Customers

Prestige Medical Limited
East House, Duttons Way,
Shadsworth Business Park,
Blackburn BB1 2QR

Tel : +44 (0) 1254 682 622
Fax : +44 (0) 1254 682 606

www.prestigemical.co.uk
sales@prestigemical.co.uk

Overseas Customers

Contact your local distributor. In case of doubt contact Prestige Medical.

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Model no.

Date of purchase

Serial no.

 **Prestige Medical**[®]
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 0086



BS EN ISO 9001:2000
Cert No. FM31988 | ISO 13485:2003
Cert No. FM79156

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Registered in England
Reg No. 2826793

Section 1: Introduction

Thank you for choosing the Prestige Medical Classic PodiaClave Autoclave designed to sterilize solid unwrapped instruments.

After removing from the box, please check for any transit damage, if damage to the box is found, please contact your supplier immediately.

Together with this unit and operating manual, you will find the following:

- Instrument furniture
- Electrical mains cord
- Warranty registration card
- Certificate of Compliance (230V Models Only)
- Spare fuses x2 (230v models only)
- Printer and power supply
- Performance test certificate
- Printer cable

Section 2: Operating symbols, displays and controls

The following descriptions refer to the pictures of the controls, display lights and operating symbols opposite.

Controls:

- A Depressurization Valve
 B Start Cycle Button
 C Pressure Rise Indicator
 D Display Panel
 E Top Handle - **WARNING HOT PART!**
 Do not touch the top handle immediately after a cycle.
 Do not use to open the lid.
 Do not carry the autoclave when HOT.
 F Steam Duct - **WARNING HOT PART!**
 Do not cover!

Display lights:

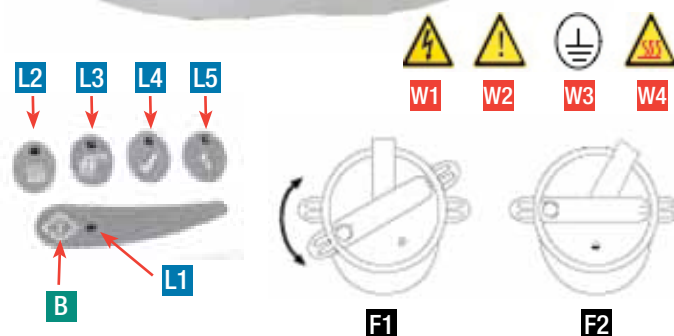
- | | |
|-------------------------------|--------------------|
| L1 Power "On" light | illuminates GREEN |
| L2 Heating light | illuminates ORANGE |
| L3 Sterilizing light | illuminates YELLOW |
| L4 Sterilizing complete light | illuminates GREEN |
| L5 Fault light | illuminates RED |

Figures:

- F1 Lid aligned with body, turn clockwise to close
 F2 Lid in closed position

Warning symbols:

- W1 Caution, electric shock hazard
 W2 Warning, read manual before using the autoclave
 W3 Warning, unit must be earthed/grounded
 W4 Warning, heat hazard



WARNING!

Do not touch the body or lid as these parts become hot when the autoclave is in operation.



Section 3: Getting started

Before using the autoclave for the first time please take time to read the following pages to familiarise yourself with the operation of the unit.

We strongly recommend that all users of the autoclave are trained in its operation.

The autoclave is very easy to use. By following this simple operating sequence in conjunction with the pictures of the autoclave, its controls, display panel and operating symbols (page 3), you will be able to ensure your instruments are correctly sterilized every time.

WARNING!


The mains outlet **MUST BE EARTHED (GROUNDED)**.
The mains plug should always be easily accessible as it is to be relied upon as “the means of disconnection”.

3.1 Water

Fill the unit to the water level line on the inside of the chamber with 0.75l of distilled or de-ionised water.

DO NOT USE TAP WATER OR OVERFILL.

3.2 Loading


 Place UNWRAPPED and WASHED instruments ONLY plus a TST Strip into the instrument basket or cassettes, and place in the unit.

TST strips should be placed as near to the centre of the load as possible (available as an accessory).

WARNING!

The manufacturers of instruments should be consulted about their suitability for autoclaving and the maximum temperature which the instruments can withstand.

3.3 Closing

 Always place the lid on the autoclave with the Depressurization Valve (A) open. Align the lid and body (F1) and turn in a clockwise direction ensuring the lid is completely closed (F2). Close the Depressurization Valve (A) so it is aligned with the top handle on the lid. Never leave in position as shown in F1.

3.4 Power connection

Attach the cable supplied to the rear of the unit and plug into an EARTHED mains electrical socket of the CORRECT voltage. Lights: L1 illuminates GREEN.

3.5 Starting

Start the sterilizing cycle by pressing button (B).

Lights: L1 illuminates GREEN
L2 illuminates ORANGE

- as the temperature rises, air will be displaced by steam through the Air Bleed Device located in the lid, until it closes with an audible “click”, sealing the unit.

The Pressure Indicator (C) will rise indicating the unit is now pressurised.

Sterilizing Temperature is reached when:

Lights: L1 illuminates GREEN
L2 flashes ORANGE
L3 illuminates YELLOW

Sterilizing Cycle is completed when:

L1 illuminates GREEN
L4 illuminates GREEN

Note: L4 remains GREEN until a new cycle is started or the unit is disconnected from the mains power.

NB The cycle data printout will contain the date and time set to GMT. There is currently no user facility to adjust for BST. This does not effect the integrity of the data.

3.6 Depressurizing

Once the sterilizing cycle has been completed, the unit needs to be depressurized and allowed to cool down before the lid and sterilized instruments can be removed. The time taken to reach the point at which this is safe to do so can be shortened by manually depressurizing the unit.

Open the Depressurization Valve (A) by turning slowly in an anti clockwise direction*. The Pressure Indicator (C) will drop once the steam has been released.

WARNING!

There will be a visual and audible release of steam from the rear of the Steam Duct (H).

3.7 Unlocking

Once the pressure has been released the lid may be unlocked. Ensure the Depressurization Valve (A) is open. Remove the lid by turning in an anti-clockwise direction (F1).

Section 4: Continued operation

3.8 Unloading

Lift off the lid, gently place upside down on a solid work surface and leave to cool. Ensure the Depressurization Valve (A) is in the closed position to avoid damaging it.

The unit has completed a successful cycle if the “spot” on the TST Indicator Strip has completely changed colour from yellow to purple.*

The basket or cassettes containing the sterilized instruments can now be lifted out of the unit. To avoid damage, replace the lid as described in step “3.3”.

*Please Note: If the “spot” has not completely changed colour, replace with a new TST strip and start a new cycle. If the “spot” fails to change colour for a second time, do not use the unit until it has been checked by a qualified engineer.

STERILIZATION CYCLE HAS NOT BEEN ACHIEVED

3.9 Cycle verification

We recommend the use of a 134°C TST strip process challenge device. Simply place the indicator strip in with the load. Prestige Medical can supply TST strips – order part no. 219277.

To ensure your autoclave gives you the years of service for which it was designed, it is important to remember a few “do’s” and “don’t’s” with regards to the operation of the unit and to carry out simple care and maintenance procedures on a weekly basis.

Do ensure that....

- 1...you read these instructions and always follow the operating sequence.
- 2...the work surface on which you will place the autoclave is flat, solid and heat resistant.
- 3...the instruments are designed to withstand the sterilizing temperatures selected, are thoroughly cleaned and rinsed before sterilizing, and are not any longer than the length, or exceed the load weight, specified – see “Technical data” section.
- 4...the water level is maintained regularly with clean distilled or de-ionised water only.
- 5...the unit is in a “draught free” environment and is positioned not less than 250mm from adjacent walls.
- 6...you only use green sealing gasket (219500) and that it is changed at the end of its life, if visibly damaged, or when shrinkage has occurred, see “Fault mode - 5”.
- 7...the lid is securely closed when the unit is not in use, to avoid the risk of accidental damage. Never leave in position as shown in F1.
- 8...you quote your model details, serial number and date of purchase when contacting Prestige Medical or your supplier.

Do not....

- 1...touch the unit whilst in operation - it gets HOT.
- 2...attempt to remove the lid during operation.
- 3...lose this operating instruction manual
- 4...add any chemicals whatsoever to the water.
- 5...attempt to sterilize volatile substances toxic materials or inappropriate loads.
- 6...place the unit on heat sensitive surfaces polished wood or glass.
- 7...open the Depressurization Valve (A) during the sterilization cycle.
- 8...leave the Depressurization Valve (A) in the “open” position when placing the lid upside down on a work surface.
- 9...immerse the unit or electrical cord in water when cleaning
- 10...use abrasive materials or lubricants when cleaning.

Section 4: Continued operation (continued)

- 11....drop or abuse the unit.
- 12....use in areas of risk associated with flammable materials or gases.
- 13....attempt to change fuses until the unit has been unplugged from the mains. Only qualified persons should change fuses.
- 14....reach over the unit when removing cover, to do so may cause burns from rising heat and steam.
- 15...press start button once cycle has been started as this will re-set the cycle timer to zero.

Care and maintenance

WARNING!

Disconnect the autoclave from the mains power supply before cleaning.

Green sealing gasket

1. Remove from inside the lid and clean with warm, soapy water.
2. Rinse thoroughly, shake dry, do not wipe.
3. Replace in the lid by tucking evenly under all lugs starting at the Gasket Offset Device. It may appear slightly wrinkled until used.
4. Replace gasket when it begins to show signs of leakage.

Autoclave

- 1 If a new gasket leaks, or a persistent leak develops, gently clean the sealing surface of both the lid and body of the unit with a "Scotchbrite" scrubbing pad making sure you do not remove any metal. Rinse both surfaces but do not dry.
- 2 Clean both interior and exterior with warm, soapy water ensuring the electrical parts are kept dry.
- 3 Monitor the first cycle of the day to check the Air Bleed Device, which is located inside the lid, audibly "clicks" shut.
- 4 Prestige Medical recommends that your unit is calibrated at six monthly intervals.
- 5 Lubricate underside of body lugs with "vaseline" if the lid becomes stiff.

DO NOT LUBRICATE GASKET

Section 5: Trouble shooting

In the event of a fault occurring during any stage of the units operation, identify the fault by referring to the descriptions below. The fault can be rectified by following the Fault Remedy applicable to the problem incurred.

Fault indication/Description/Remedy

Fault 1: No Power to unit

Light: L1 fails to illuminate.
Blown fuse / Defective Socket /
Mains not connected
Ensure mains lead is connected.
Check / replace fuse: Check power to socket:

Fault 2: Low water or boil dry.

Light: L5 flashes RED
Allow unit to cool before refilling to the correct level. Disconnect from mains then reconnect and repeat cycle. If the fault repeats with sufficient water, arrange for a service engineer to visit.

Fault 3: Sterilization failed to be achieved.

Light: L4 fails to illuminate GREEN.
Disconnect from mains then reconnect and repeat cycle. If the fault repeats arrange for a service engineer to visit.

Fault 4: Incomplete sterilization cycle

TST strip fails to change / completely change colour. Check expiry date of TST strips. Disconnect from mains then reconnect and repeat cycle. If the fault repeats arrange for a service engineer to visit.

Fault 5: Steam or water leaks from under the lid

i) Worn or dirty gasket.
Wash gasket and sealing surfaces on the body and lid as described under "Care and Maintenance". If the fault persists, replace with a new gasket.
ii) Incorrectly closed lid.
Ensure the unit is fully depressurized by opening Depressurization Valve (A). Remove lid and re-fit carefully. Disconnect from mains, reconnect and repeat cycle.

Fault 6: Excessive steam or water leaking from

Depressurization Valve (A).
Depressurization Valve (A) in "OPEN" position
Close Depressurization Valve (A).

If the unit has been allowed to fully cool down, it is recommended that, prior to use, a warm-up cycle is run. During the course of operation the water level must be maintained up to the water level line.

Section 6: Technical specification

In the unlikely event that something should go wrong, we have incorporated a number of safety features to ensure that your autoclave remains safe at all times.

Safety features

1. Located to the rear of the lid, beneath the cover, is a spring called the Gasket Offset Device (GOD Spring), designed to prevent pressure building up if the lid has been incorrectly fitted.

DO NOT TAMPER WITH THIS SAFETY DEVICE

2. If for any reason, the temperature falls below the minimum required sterilizing temperature, resulting in the Sterilizing Temperature Light (L3) switching off, the cycle timer will re-start from zero once the correct temperature has been restored.
3. If there is an electrical or electronic failure resulting in a build up of pressure - in excess of normal operating pressure - one or all of the following safety features will be activated.
 - i) Depressurization Valve (A) will loudly and rapidly "vent" steam. The overpressure Safety Valve located underneath the handle (G) will Loudly and rapidly vent steam allowing its exit via the Steam Duct (H)
 - ii) The gasket will "extrude" through the slot in the rear of the lid rapidly releasing excess pressure and steam.
 - iii) A non - resettable thermal fuse located in the base of the unit will "melt" at a pre-determined temperature, disconnecting the power.

Technical specifications

Height	335 mm
Width	340 mm
Net Weight	5.6 kilos
Capacity	9 litres
Internal Chamber Dimensions (d/h)	210/230 mm
Max' Instrument length	228 mm
Max' Load Weight.	3.0 kilos

Should any of the devices listed activate, please observe the following steps:

- a) Do not touch the unit.
- b) Switch off at the wall socket and un-plug
- c) Allow temperature and pressure to drop before
 - i) touching the unit
 - ii) removing your instruments
- d) Do not attempt to re-start the unit
- e) Arrange for an immediate service.

Fuses - Located under the control module, fuses F10A, 32 x 6.3mm, ceramic sand filled (230v model only)
Mains plug top fuse (User replaceable), F13A to BS1362
UK ONLY.

Rating - Models are rated continuously for intermittent use.

Body - Deep drawn aluminium.

Lid - 304 Stainless Steel

Heater - Externally surface mounted mechanically fixed electric element.

Temperature cut out - Thermal fuse.

Pressure - Calibrated pressure release valve.

Max. Single Fault Temperature - 143°C

Over Voltage Category - Group II

Pollution degree - Group 2

Environment conditions - indoor use - temperature 5°C to 40°C - altitude up to 2000m - maximum relative humidity 80% for temperatures up to 31°C decreasing linearly to 50% relative humidity at 40°C. - mains supply voltage fluctuations not to exceed +10% of the nominal voltage
Input Connections - Mains inlet socket 'hot' format conforming to IEC 302.

Safety shut down - See 'Temperature Cut Out'.

Packaging - All packaging materials are recyclable

Section 7: Additional information

Spares

Only those spare parts supplied or specified by Prestige Medical should be used in the maintenance of the autoclave. Use of unauthorised parts will invalidate any warranty given and may adversely affect the performance and safety of the unit.

Accessories

A range of accessories are available for your autoclave as described and pictured below.

Contact your supplier for full details.

- 1 219748 - Green silicone sealing gasket x 4
- 2 219277 - TST indicator strips
- 3 219258 - Cord set UK



Warranty

Prestige Medical shall, in the first 12 months from the date of purchase, repair or replace free of charge any parts which prove to be defective in workmanship and/or materials.

Prestige Medical shall not be so liable in the event that the purchaser has failed to adhere to the instructions contained herein or if the autoclave has been abused, interfered with, altered, repaired or serviced by any unauthorised party this may also result in the protection provided by the equipment being impaired.

This warranty **excludes** the gasket, all internal furniture and consumables. Consumer's statutory rights are not affected.

Product decontamination

Should the unit require repair, it must be decontaminated in accordance with a recognised procedure prior to return or on-site repair. A statement of equipment contamination status must be available with the product. (Details of a suitable procedure are available on request).

Approvals

Note: please ask for details of approvals specific to your model.

BS 3970 Part 4	- Pressure vessel only
CE mark	- Medical device directive
IEC 61010	- Product safety
PD 5500	- Pressure vessel

Cleaning materials

- Mild washing up liquid
- Non-abrasive cream cleaner
- Disinfectant diluted in water - non chlorine base Packaging

All packaging materials used are recyclable, please dispose of accordingly.

WEEE Statement

(Waste Electrical and Electronic Equipment)

The WEEE directive places an obligation on all EU-based manufacturers and importers to take back electronic products at the end of their useful life.

Prestige Medical Limited accepts its responsibility to finance the cost of treatment of redundant WEEE in accordance with the specific recycling requirements.

Disposal

The symbol (shown below) is present on all Prestige Medical Products, which indicates that the product must NOT be disposed of with other waste. Instead it is the user's responsibility to dispose of their waste electrical and electronic equipment by handing it over to an approved reprocessor, or by returning it to Prestige Medical for reprocessing. For more information about where you can send your waste equipment for recycling, please contact your local city office or Prestige Medical.

